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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/293,533	04/15/99	CHATTERJEE M	304142000201

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EXAMINER	
HELMS,L	
ART UNIT	PAPER NUMBER
1642	13

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/293,533	Applicant(s) CHATTERJEE ET AL.	
	Examiner Larry R. Helms	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *62-99* is/are pending in the application.

4a) Of the above claim(s) *64-67 and 78-81* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *62-63, 68-77, 82-99* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 90-99 have been added.
2. Claims 64-67, 78-81 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Election was made without traverse in Paper No. 8.
3. Claims 62, 63, 68-77, and 82-99 are under examination and will be examined to the extent the GD2-associated tumor is melanoma.
4. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

5. The following Office Action contains some NEW GROUNDS of rejection.

Information Disclosure Statement

6. The Examiner acknowledges that applicants will address the request of supplying additional copies of references 23-102 of PTO-1449 submitted 4/15/99 under a separate cover. The Examiner has checked application 08/591196 and the references were not supplied in the application. The IDS has been placed in the file and if Applicants would supply the Examiner with the copies of the references the Examiner will then consider the references.

Rejections Withdrawn

7. The rejection of claims 62, 63, 68-74 under 35 U.S.C. 112, first paragraph, is withdrawn in view of the declaration by Dr. Foon.

Response to Arguments

8. The rejection of claims 75, 89 and newly added claim 99 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained.

The response filed 5/29/01 has been carefully considered but is deemed not to be persuasive. The response states "Applicants respectively submit that the meaning of the phrase "heat-treating an antibody" would be evident to one skilled in the art." (see page 6-7 of response of 5/29/01). In response to this argument, as stated previously it is not clear what temperature is intended or what is "heat-treating an antibody". The phrase does not seem to be art recognized because a search of the patent database did not indicate any patents with this phrase.

9. The rejection of claims 75, 89, and newly added claim 99 under 35 U.S.C. 112, first paragraph, is maintained.

The response filed 5/29/01 has been carefully considered but is deemed not to be persuasive. The response states "Applicants reiterate the points set forth above in discussing the §112, second paragraph rejection" and "it is evident, therefore, that one skill in the art would be able to determine an appropriate heating temperature that would achieve functional embodiments of the claimed methods" (see page 8 of response). In response to these arguments, again the claims encompass any temperature. While a temperature that causes denaturation of the antibody would not be an "appropriate heating temperature" the claims encompass any

temperature and time and the specification only enables heating to about 48°C for about 30 minutes.

Therefore, in view of the lack of guidance in the specification and in view of the discussion above one of skill in the art would be required to perform undue experimentation in order to practice the claimed invention.

Priority

10. Applicants claim for U.S. Priority to 08/752,844 now U.S. Patent 5,935,821, 08/591,196 now U.S. Patent 5,977,316, and 08/372,676, now U.S. Patent 5,612,030, is acknowledged. The response filed 5/29/01 has been carefully considered but is deemed not to be persuasive. The response states that a deposit of the hybridoma producing the1A7 antibody was disclosed and deposited in the 08/372,676 application and the sequences contained within the antibody were also inherently disclosed (see page 9 of response). In response to this argument, it may be true that it is inherent that the 1A7 antibody contains the sequence of SEQ ID Nos 2 and 4, however, the limitations of any antibody comprising the light and heavy chain variable region sequences in SEQ ID Nos 2 and 4 are not seen in the 08/372,676 application. The claims encompass any antibody comprising SEQ ID Nos 2 and 4 not just the entire IgG 1A7 antibody. This limitation is not seen in the 08/372,676 application. The limitation is seen in both 08/591,196 and 08/752,844 where it is disclosed that the 1A7 antibody comprises a scFv (see column 24, lines 49-62, for example in patent 5,977,316) or Fab fragments (see column 14, lines 65-66 in patent 5,977,316 for example). Therefore, claims 62-99 are granted the priority date of application 08/591,196, now U.S. Patent 5,977,316, filed 1/16/96, for which an antibody comprising SEQ ID Nos 2 and 4 are disclosed.

11. The rejection of claims 62-63, 68-77 and 82-99 under 35 U.S.C. 103(a) as being unpatentable over Chatterjee et al (U.S. Patent 5,612,030, filed 1/17/95) and further in view of Harlow et al (Antibodies, A Laboratory Manual, Cold Spring Harbor Laboratory, pages 96-99, 1988) is maintained.

The response filed 5/29/01 has been carefully considered but is deemed not to be persuasive. The response states that "the present claims are entitled to the priority date of application 08/372,676, now U.S. Patent 5,612,030, which was filed 1/17/95." (see page 10 of response). In response to this argument, the priority was addressed supra. In addition, claims 62-63, 68-75 and newly submitted claims 90-99 are included in the rejection because Chatterjee et al teach the 1A7 antibody and a method of treating melanoma with the antibody administered at 2mg using an adjuvant QS-21(see column 6-7 and column 11, lines 13-22) and the antibody generates an immunity to GD2 which is expressed on malignant melanoma cells (column 4, lines 60-64). Chatterjee et al also teach administering at bi-weekly intervals of the antibody in Freund's adjuvant (column 6, lines 30-34) and the "effective dosage for mammals may vary due to such factors as age, weight, activity level or condition of the subject being treated." (Column 11, lines 13-15). Harlow et al, teach adjuvants of aluminum hydroxide. Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have used the 1A7 antibody of Chatterjee et al and an adjuvant of aluminum hydroxide as taught by Harlow et al for a method of treatment of tumor. In addition, it would be obvious to one of ordinary skill in the art at the time of the claimed invention that a method of treatment also includes delaying recurrence when treatment elevates symptoms. In addition, Chatterjee et al teach "the method may be administered to a patient who...remains at high risk of recurrence of metastatic melanoma" (see column 5, lines 6-10). Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

12. The rejection of claims 76-77, 82-89 and newly added claims 90-99 under 35 U.S.C. 103(a) as being unpatentable over Chatterjee et al (J. Immunol. 150 (8 part 2) 142A Abstract 805, 1993) and further in view of Saleh et al (the Journal of Immunology 151:3390-3398, 1993) and Harlow et al (Antibodies, A Laboratory Manual, Cold Spring Harbor Laboratory, pages 96-99, 1988) is maintained.

The response filed 5/29/01 has been carefully considured but is deemed not to be persuasive. The response states that the Chatterjee et al reference does not provide an enabling disclosure as they did not disclose the sequences of the light and heavy chain variable regions nor was the antibody publicly available at the time of the publication of the reference. (see page 10 of response). In response to this argument, it is noted that declarations filed 3/18/96 by S. Chatterjee and M. Chatterjee in application 08/372,676 states that the sequences and the 1A7 antibody or hybridoma was not publicly available at the time of the publication of the J. Immunol. abstract. No copy of these declarations are present in the instant application and a copy of these declarations would be sufficient to obviate this rejection. . In addition, the response states that evidence obtained in a rabbit model would not correlate with results expected in humans (see page 13 of response). In response to this argument, the claims recite an "Individual" which as defined in the specification on page 21, lines 10-11, individual is "a vertebrate, preferably a mammal". Based on this definition a rabbit is an "individual".

13. The rejection of claims 76-77 and 82-89 and newly added claims 90-99 under 35 U.S.C. 103(a) as being unpatentable over Chatterjee et al (J. Immunol. 150 (8 part 2) 142A Abstract 805, 1993) and further in view of Cheung et al (Int. J. Cancer 54:499-505, 1993) and Harlow et al (Antibodies, A Laboratory Manual, Cold Spring Harbor Laboratory, pages 96-99, 1988) is maintained.

The response filed 5/29/01 has been carefully considered but is deemed not to be persuasive. The response states that the Chatterjee et al reference does not provide an enabling disclosure. In response to this argument, it is noted that declarations filed 3/18/96 by S. Chatterjee and M. Chatterjee in application 08/372,676 states that the sequences and the 1A7 antibody or hybridoma was not publicly available at the time of the publication of the J. Immunol. abstract. No copy of these declarations are present in the instant application and a copy of these declarations would be sufficient to obviate this rejection. In addition, the response states that evidence obtained in a mouse model would not correlate with results expected in humans (see page 14 of response). In response to this argument, the claims recite an "Individual" which as defined in the specification on page 21, lines 10-11, individual is "a vertebrate, preferably a mammal". Based on this definition a mouse is an "individual".

Conclusions

14. No Claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

16. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official

Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Respectfully,

SHEELA HUFF
PRIMARY EXAMINER

Larry R. Helms Ph.D.

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